REMARKS

Claims 1-3, 5, 13, 15-18, 20-23, 33-35, 39-43, 45-47 and 49 are currently pending. Claims 4, 6-12, 14, 19, 24-31, 37 and 38 were previously cancelled and claims 32, 36, 44 and 48 are currently cancelled. Claim 1 is currently amended in accordance with the Examiner's suggestion and support can be found, for example in Figures 1-8. Claim 2 is amended to be consistent with amended claim 1. Claim 34 is currently amended in accordance with the Examiner's suggestion and support can be found, for example in Figure 2 and 8. Claim 35 is amended to depend from claim 34. Claim 41 is amended to depend from claim 1. Clam 47 is amended to be independent. No new matter is added.

Drawing Objection

The drawings are objected to for allegedly failing to show the "center of the concavity of the first surface is in contact with the second surface." The Examiner is directed to Figure 8, as amended on January 25, 2007 (an as originally submitted in the non-formal drawings), which shows a section 60b of opening 60 is closed near tip 90 (see paragraph [0022]).

35 USC 112 Rejection

Claims 47 and 48 are rejected under 35 U.S.C. 112, 2nd paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner states that "the new limitations would contradict the scope of the independent claim, since the opening wouldn't be a U-shaped opening anymore" (Office Action, page 3). Claim 47 has been amended to be an independent claim and claim 48 has been cancelled, thus Applicants believe this rejection is moot.

35 USC 102 Rejection over Ayres

Claim 34 is rejected under 35 U.S.C. 102(b) as allegedly anticipated by US Patent No. 3,906,932 to Ayres ("Ayres"). Applicants respectfully traverse this rejection because Ayres does not describe each and every element of claim 34. Ayres also does not disclose a catheter or syringe having a needle connected to a distal end thereof, as claimed. Furthermore, it would not be obvious to modify Ayres as such, since the needle 40 is intended to puncture a stopper of a test tube (Fig. 5), not to deliver a drug.

Ayres describes a needle 40 having a opposed bevel faces 12 and 14 that are angled towards each other so that flat tips 16, 18 form an hourglass shape when viewed from the distal end, along a longitudinal axis (Fig. 4). Thus, although the opening at the distal end, may appear to have a U-shape when viewed from the side, it does not have a U-shaped opening when viewed along the longitudinal axis from the front of the distal end, as amended claim 34 states. For at least these reasons, claim 34 and all claims dependent therefrom, are not anticipated by Ayres. Applicants thank the Examiner for the suggestion to amend the claim to state "wherein viewed along the longitudinal axis from the front of the distal end" and have amended claim 34 to include this amendment to expedite prosecution.

35 USC 102 Rejection over Larson

Claims 1, 2, 5, 13, 15-18, 20, 22, 36, 41, 45 and 46 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by US Patent No. 4,020,837 to Larson ("Larson"). Applicants respectfully traverse this rejection because Larson does not describe each and every element of the claims. Larson describes a hollow piercing tip for vial stoppers having a sharpened tip end 12.

A. Claims 1, 2 and 5

Larson does not disclose a drug delivery device, as the needle structure 10 is only intended to puncture a seal of a medicament vial, not to deliver a medicament to a patient. Furthermore, although Larson does disclose a needle, the distal opening of the needle does not have a smaller cross-sectional area than a section of the shaft proximal to the distal end. Center bore 22 has the same projected area at the distal end as it does throughout the whole shaft (Figs. 2 and 5). Although the wall portion 24 has bevels 18 and 20, these bevels do not change the cross-sectional area *of the opening* at the end, but only alter the thickness of the wall (Fig. 5). The Examiner refers to the projected area as 20+22, however 22 is the center bore and 20 is the inner partially annular bevel in the wall 24. Thus, 20 does not form part of the distal *opening*, but rather forms the wall defining the opening.

The Examiner states that "the distal opening has a tapered section and the area of the tapered section would be less than the area of the lumen at the proximal end" (Office Action, page 7). However, only the thickness of the wall is tapered, not the opening. The projected area of the distal opening in Larson would be the same as a cross-sectional area of the opening of the

shaft proximal to the distal end, as can be seen from the front end view in Fig. 2 and the longitudinal section view in Fig. 5 (showing a section taken along line 5-5 in Fig. 4). The lumen is not covered at all by the beveled areas 26. The Examiner appears to be relying on Figure 4, however this is a top view and thus does not show the full distal opening from this angle. The Examiner also appears to misunderstand the limitation of the "cross-section area" and claim 1 has been amended to clarify. The Examiner "would also like to note that the claim states a cross section of a section of the shaft proximal to the distal end, and never recited the length of the section that is going to used to determine the area" (Office Action, page 7). The cross-sectional area has a negligible length as it just represents a slice taken at a point along the shaft and the area of the opening at that point. Thus, no length is necessary for such a determination.

For at least these reasons, claim 1 and all claims dependent therefrom, are not anticipated by Larson. Applicants thank the Examiner for the suggestion to amend the claim to state "the first surface covering a majority of the distal opening" and have added this limitation to claim 1 to expedite prosecution.

With respect to dependent claim 2, Larson does not disclose a distal end having opposing first and second surfaces, wherein the first surface is indented towards the second surface to form a *concavity* on an outer potion of the first surface. According to the American Heritage Dictionary, a concavity has a surface curved like the inner surface of a sphere. Larson describes a beveled surface 18, which means a straight surface angled at a certain degree, as shown in Fig. 5. The surface of the needle in Larson has no curve and thus cannot form a "concavity". Thus, for at least these reasons, claim 2 is not anticipated by Larson.

B. Claims 13, 15, 16, 22, 23, 45 and 46

Larson does not disclose a method of delivering a therapeutic agent to a target site, or a method of collecting a fluid sample from a body, as recited in claims 13 and 22 respectively. As discussed above, Larson does not disclose a needle with a *concavity* on the outer surface thereof, or a distal opening having a projected cross-sectional area smaller than a section of the shaft proximal to the distal end. Furthermore, the device of Larson is not used directly with the human body. Thus, Larson does not describe the steps recited in claim 13 of puncturing a body tissue or delivering a therapeutic to a target site of a body though the needle or the steps recited in claim 22 of inserting the needle into a fluid containment site of the body, and creating a vacuum in the

drug delivery device to collect a fluid sample from the fluid containment site of the body. The Examiner states that "Larson states the needle can be used with a syringe that takes the medicine from the vial and thus treating the patient" (Office Action, page 8). However this still fails to specifically address the recited method steps. Furthermore, Larson only describes puncturing a stopper of a medicament vial and is specifically designed to have a strength to puncture the seal, thus it would not be obvious to use such a device to puncture body tissue. For at least these reasons, claims 13 and 22 and all claims dependent therefrom are not anticipated by Larson.

With respect to dependent claim 15, 16, 23, 45, 46, the Examiner does not address any of these limitations. Larson does not disclose delivering a therapeutic to any target site by any method, let alone a specific target site as recited in claims 15, 45 and 46 or the specific delivery method as recited in claim 16 also is not disclosed. Additionally, since Larson does not disclose collecting any fluid sample from the body, a specific fluid as recited in claim 23 also is not disclosed. For at least these reasons, claims 15, 16, 23, 45 and 46 are not anticipated by Larson.

C. Claims 17, 18, 20, 36 and 41

With respect to independent claims 17 and 36, Larson does not disclose a needle with a concavity on the outer surface thereof, or a distal opening having a projected cross-sectional area smaller than a section of the shaft proximal to the distal end, as discussed above. For at least these reasons, claims 17 and 36 and all claims dependent therefrom are not anticipated by Larson.

35 USC 102 Rejection over Ferguson

Claim 36 is rejected under 35 U.S.C. 102(b) as allegedly anticipated by US Patent No. 2,560,162 to Ferguson ("Ferguson"). Claim 36 is cancelled, thus this rejection is moot.

35 USC 102 Rejection over Magasi

Claims 34, 35, 47 and 48 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by US Patent No. 4,826,492 to Magasi ("Magasi"). Applicants respectfully traverse this rejection because Magasi does not describe each and every element of claims 34 and 35. However, Magasi does not show such a form of a needle *during use*, as claimed. Applicants respectfully request withdrawal of this rejection.

35 USC 103 Rejections over Ayres and Jansen

Claim 1 is rejected under 35 U.S.C. 103(a) as allegedly obvious over Ayres in view of US Patent No. 6,626,864 to Jansen et al. ("Jansen"). As discussed above, Ayres does not disclose a drug delivery device, a catheter, or a syringe. Ayres also fails to disclose a distal end comprising opposing first and second surfaces, wherein the first surface blocks a majority of the distal opening, as recited in claim 1. Jansen describes a safety shield system for prefilled syringes and does not cure the deficiencies of Ayres. Thus, claim 1, and all claims dependent therefrom, is not obvious over Ayres in view of Jansen.

35 USC 103 Rejections over Ayres, Jansen and Alchas

Claims 3, 5, 39 and 42 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Ayres in view of Jansen in further view of US Patent No. 4,537,593 to Alchas ("Alchas"). Ayres and Jansen do not describe all the limitations of claim 1, as discussed above, and Alchas cannot make up for these deficiencies. Alchas describes a closed sharp pointed tip. Thus, claim 1, and all claims dependent therefrom, is not obvious over Ayres in view of Jansen in further view of Alchas.

With respect to claims 3 and 42, the Examiner uses Alchas for the disclosure of aperture 36, stating it would have been obvious to incorporate the aperture into the device of Ayres "in order to vent air." However, there is no teaching, suggestion or motivation to use such a vent in Ayres. It would not be obvious to one of ordinary skill in the art to vent air from Ayres' device for puncturing test tube stoppers, since such an air vent could lead to undesirable contamination of samples housed in the test tube. For at least these reasons, claims 3, 5, 39 and 42 are not obvious over Ayres in view of Jansen in view of Alchas.

35 USC 103 Rejections over Larson and Alchas

Claim 44 is rejected under 35 U.S.C. 103(a) as allegedly obvious over Larson in view of Alchas. Claim 44 is cancelled, thus this rejection is moot.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

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